

7. REGULATIONS AND ADVISORIES

The international, national, and state regulations and guidelines regarding 4,4'-methylenedianiline in air, water, and other media are summarized in Table 7-1.

ATSDR has derived an acute oral MRL of 0.2 mg/kg/day based on a minimal LOAEL for liver effects observed in rats treated with a single dose of 4,4'-methylenedianiline (Bailie et al. 1993).

ATSDR has derived an intermediate oral MRL of 0.08 mg/kg/day based on a NOAEL for liver effects observed in rats treated daily with gavage doses of 4,4'-methylenedianiline for 12 weeks (Pludro et al. 1969).

Neither a reference dose nor a reference concentration for 4,4'-methylenedianiline is available at this time.

The International Agency for Research on Cancer (IARC) has classified 4,4'-methylenedianiline as 2B, probably carcinogenic to humans, based on limited evidence of carcinogenicity in humans but sufficient evidence of carcinogenicity in animals (IARC 1987). The EPA and the National Toxicology Program (NTP) have not classified the chemical for carcinogenicity. The National Institute for Occupational Safety and Health (NIOSH) has identified 4,4'-methylenedianiline as a potential occupational carcinogen and recommends that occupational exposures to the compound be limited to the lowest feasible concentration (NIOSH 1994).

4,4'-Methylenedianiline is on the list of chemicals appearing in The Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) (EPA 1987). Section 313 of Title III of EPCRA requires owners and operators of certain facilities that manufacture, import, process, or otherwise use the chemicals on this list to report annually their release of those chemicals to any environmental media.

OSHA requires employers of workers who are occupationally exposed to 4,4'-methylenedianiline to institute engineering controls and work practices to reduce and maintain employee exposure at or below permissible exposure limits (PEL). Except as provided by specific clauses within the standard given at 29 CFR 1910.1050 (e.g., products not capable of releasing MDA in excess of the action level;

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conditions where no dermal exposure to MDA can occur, materials in any form containing less than 0.1% MDA by weight or volume, and construction work) for all occupational exposures to MDA, the employer must use engineering and work practice controls, if feasible, to reduce exposure to or below an 8-hour time-weighted average (TWA) of 10 ppb (OSHA 1992a, 1992b). The short term exposure limit (STEL), as determined by any 15minute sampling period is 100 ppb (OSHA 1992a, 1992b). The OSHA standard for construction work is given in 29 CFR 1926.60; however, the PEL for these activities is the same as that for all other occupational exposures. The action level for occupational exposure to airborne 4,4'-methylenedianiline, including construction work, is 5 ppb, based on an 8-hour time-weighted average (OSHA 1992a, 1992b). The OSHA standard for construction work is applicable, but not limited, to activities such as alteration, repair, maintenance, or renovation of structures or substrates that contain 4,4'-methylenedianiline (OSHA 1992a, 1992b). Respirators must be provided and used during the time period necessary to install or implement feasible engineering and work practice controls (OSHA 1992a, 1992b).

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Table 7-1. Regulations and Guidelines Applicable to 4,4'-Methylenedianiline

Agency	Description	Information	References
<u>INTERNATIONAL</u>			
Guidelines:			
WHO			NA
IARC	Group (cancer ranking)	Sufficient Evidence of Carcinogenicity to Experimental Animals Group 2B	IARC 1987
<u>NATIONAL</u>			
Regulations:			
a. Air:			
OSHA	Permissible Exposure Limit (TWA)	Airborne: 10 ppb as an 8-hour time-weighted average	29 CFR 1910.1050 OSHA 1992a ^a and 29 CFR 1926.60 OSHA 1992b ^a
	Permissible Exposure Limit (Ceiling)	Dermal: Eye and skin contact (not permitted)	
	Short term exposure limit (STEL)	100 ppb	
	Action Level for Occupational Exposures	5 ppb	
EPA OAR	Hazardous Air Pollutants (HAPs)	Yes	Clean Air Act Amendment Title III, Section 112 (b) U.S. Congress 1990
	Standards of Performance for New Stationary Sources		40 CFR 60.489 EPA 1981
	equipment leaks of VOC in the SOCMII-list of chemicals produced by affected facilities	Yes	
	National Emission Standards for Hazardous Air Pollutants (NESHAPs) from Source Categories-organic hazardous air pollutants from SOCMII	Yes	40 CFR 63.106 EPA 1994
	National Emission Standards for Wood Furniture Manufacturing Operations	Yes	40 CFR 63, Subpart JJ EPA 1995b
	Table 2- list of volatile hazardous air pollutants; Table 4-pollutants excluded from use in cleaning and washoff-solvents; Table 6-VHAP of potential concern		
b. Water			
EPA OW	Effluent Guidelines and Standards organic chemicals, plastics, and synthetic fibers	Yes	40 CFR 414.70 EPA 1992

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Table 7-1. Regulations and Guidelines Applicable to 4,4'-Methylenedianiline (cont.)

Agency	Description	Information	References
<u>NATIONAL</u> (cont.)			
c. Other:			
EPA OSW	Interim Status Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities	Yes	40 CFR 265, App. VI EPA 1996
EPA OEER	Designation, Reportable Quantities, and Notification designations of hazardous substances	1 pound ^b (0.454 kg) (statutory) 10 pounds (4.54 kg) (final RQ)	40 CFR 302.4 EPA 1995c
	Toxic Chemical Release Reporting: Community Right-to-Know -applicable chemicals and chemical categories	Effective date January 1, 1987)	40 CFR 372.65 EPA 1987
FDA	Indirect Food Additives: Adhesives and Components of Coatings substances for use as components of coatings-resinous and polymeric coatings	Yes	21 CFR 175.300 FDA 1977a
	Indirect Food Additives: Polymer substances for use as basic components of single and repeated use food contact surfaces-polyurethane resins	Yes	21 CFR 177.1680 FDA 1977b
	substances for use only as components of articles intended for repeated use-4,4'- isopropylidenediphenolepichlorohydrin thermosetting epoxy resins	Yes	21 CFR 177.2280 FDA 1977c
Guidelines:			
ACGIH	Ceiling Limit for Occupational Exposure (TWA)	0.1 ppm (skin) 0.81 mg/m ³ (skin)	ACGIH 1996
NIOSH	Recommended Exposure Limit for Occupational Exposure (TWA)	Potential occupational carcinogen; lowest feasible concentration (0.03 mg/m ³ LOQ)	NIOSH 1994
<u>STATE</u>			
Regulations and Guidelines:			
a. Air:	Average Acceptable Ambient Air Concentrations Guidelines or Standards		NATICH 1992
CT	8 hours	8 µg/m ³	
FL (Ft. L'dle)	8 hours	8x10 ⁻³ mg/m ³	
FL (Pinellas Co.)	8 hours 24 hours	8 µg/m ³ 1.92 µg/m ³	
KS	Annual	4x10 ⁻² µg/m ³	
KS-KC	Annual	4x10 ⁻² µg/m ³	

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Table 7-1. Regulations and Guidelines Applicable to 4,4'-Methylenedianiline (cont.)

Agency	Description	Information	References
<u>STATE</u> (cont.)			
ND	NA	BACT	
NV	8 hours	$1.90 \times 10^{-2} \text{ mg/m}^3$	
NY	Annual	$2.70 \times 10^{-1} \text{ } \mu\text{g/m}^3$	
OK	24 hours	$8 \text{ } \mu\text{g/m}^3$	
SC	24 hours	$4 \text{ } \mu\text{g/m}^3$	
TX	30 minutes Annual	$8.10 \text{ } \mu\text{g/m}^3$ $8.10 \times 10^{-1} \text{ } \mu\text{g/m}^3$	
VA	24 hours	$8.10 \text{ } \mu\text{g/m}^3$	
WA-SWEST	24 hours	$2.60 \text{ } \mu\text{g/m}^3$	

^a OSHA 1992 denotes the effective date (September 9, 1992) for the standard.

^b Indicates that the statutory source for designation of this hazardous substance under CERCLA is CWA Section 3(b)(4).

ACGIH = American Conference of Governmental Industrial Hygienists; BACT = Best Available Control Technology; CERCLA = Comprehensive Environmental Response, Compensation, and Liability Act; CFR = Code of Federal Regulations; CWA = Clean Water Act; DOT = Department of Transportation; EPA = Environmental Protection Agency; IARC = International Agency for Research on Cancer; LOQ = Limit of Quantitation; NAAQS = National Ambient Air Quality Standard; NATICH = National Air Toxics Information Clearinghouse; NIOSH = National Institute for Occupational Safety and Health; OERR = Office of Emergency and Remedial Response; OSHA = Occupational Health and Safety Administration; OWRS = Office of Water Regulations and Standards; PAH = Polycyclic Aromatic Hydrocarbons; PEL = Permissible Exposure Limit; RCRA = Resource Conservation and Recovery Act; REL = Recommended Exposure Limit; RfD = Reference Dose; STEL = Short Term Exposure Level; TLV = Threshold Limit Value; TWA = Time Weighted Average; u.f. = Uncertainty Factor; VHAP = Volatile Hazardous Air Pollutants; WHO = World Health Organization

